

AMENDMENTS TO THE SPECIFICATION

Please replace the section entitled "Brief Description of the Drawings," with the following replacement section:

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Figure 1 is a perspective view of a securement device in accordance with the teachings of the invention;

[0011] Figure 2 is a perspective view of the device of Figure 1 showing a connector mounted thereto;

[0012] Figure 3 is an exploded view of the base, pad and backing of the device of Figures 1 and 2 illustrating a pair of flexible strands extending through aligned holes in the base and pad;

[0013] Figure 4 is a side view, in section, illustrating the interior structure of the base of the device of Figures 1 to 3;

[0014] Figures 5 and 6 are top plan views of two different modifications of the base alone of the device of Figures 1 to 4;

[0015] Figure 7 is a perspective view of a portion of another embodiment of the base of Figure 1;

[0016] Figure 8 is a view similar to Figure 5 showing still another modification of the base of Figure 1; and

[0017] Figure 9 is a side view, in section, of the base of Figure 8.

Please replace the section entitled "Detailed Description of the Preferred Embodiment," with the following replacement section:

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0018] Referring now to Figure 1, a securement device 10 is shown adapted to be used in connection with a catheter type conventional fluid line connector 12 (Figure 2). It is to be understood that, although illustrated as to be used with a catheter, the securement device 10 herein can be used with other types of medical devices or articles such as, for example, CVCs, PICCs, Foley catheters, hemodialyses catheters, surgical drainage tubes, feeding tubes, chest tubes, nasogastric tubes, or with wires or cables coupled to external or implanted electronic devices or sensors. Thus, as used herein, "medical devices or articles" means generally any

Appl. No. : **10/789,892**
Filed : **February 26, 2004**

suitable or generic type catheter, fluid supply and drainage line, connector, adaptor, electrical wire or cable, etc. which may be retained by the securement device herein and used to introduce fluids or allow drainage or the like through medical devices into or out of the patient's body.

[0019] Securement device 10 thus includes a base 14 adapted to be secured to an anchor pad 25 (Figure 3) and one or more filaments or strands, such as 2 strands 16, 24 (Figures 2 and 3) that extend from base 14.

[0020] Base 14 is secured to anchor pad 25 which is configured as shown (generally referred to as a butterfly configuration) and secured thereto in any suitable manner, such as by a solvent bond adhesive.

[0021] One or more holes 26 through 29 (Figure 3) are provided through pad 25 aligned with holes 18 to 21 (Figure 1), respectively, in base 14.

[0022] In the example shown, two such strands 16, 24 are shown adapted to be fed through holes 18 through ~~20~~ 21 (Figure 1) in base 14 and aligned holes 26 to 29 in pad 25. Thus, one strand 16 may be fed alone through aligned holes 19, 27 and up through aligned holes 29, 21 and the other strand may extend down through aligned holes 18, 26 and up through aligned holes 28, 20. Of course, any suitable number of strands and holes may be used.

[0023] Each strand 16, 24 may have a pointed distal end 22 (Figure 2) which may be hardened, such as a lacquered tip. Any suitable strand length may be used depending on the application.

[0024] The anchor pad 25 may be of flexible material as is well known in the art and may comprise a layer of a closed cell, low-density polyethylene foam and a bottom layer of a medical grade adhesive. A removable paper or plastic backing 30 (see Figures 3 and 4), conforming to anchor pad 25, covers the bottom adhesive surface of pad 25 before use. The backing 30 is of a suitable material to resist tearing and may be divided into a plurality of pieces, such as 2, for ease in attachment of pad 25 to the patient's skin. Preferably, backing 30 is of 2 pieces, adhesively attached to the bottom of pad 25 at its center 31 (Figure 3) having end portions unattached to pad 25 which can be pulled apart to expose one half of the adhesive pad at a time. Other means may be used, such as a single piece of backing which has a portion extending beyond the edge of pad ~~16~~ 25 to ease removal as is well known in the art.

[0025] Base 14 is comprised of two parts (Figure 3), an upper support base 32 secured to a lower part or support plate 33 which in turn is secured to pad 25. Plate 33 is preferably of a polycarbonate material glued or otherwise secured to pad 25.

[0026] Support base 32 may be of a suitable molded polymeric material having an upper surface covering with a plurality of upstanding generally conically shaped protrusions 34 (Figure 4) extending upwardly therefrom.

[0027] A spring beam 35 is mounted internally or integrated into support ~~base 32~~ plate 33 for reasons to be discussed.

[0028] Holes 18 through 21 in support base 32 are aligned with like holes (Figure 3 ~~not shown~~) through support plate 33 which holes are also aligned with holes 26 to 29, as previously discussed.

[0029] As seen in Figure 4, holes 18 to 21 are circular through the beam 35. The edges of each hole are radiused (see radiused wall portion 38 - Figure 4).

[0030] As seen in Figure 4, the protrusions 34 may vary in overall height and are preferably of a suitable elastomeric material. Strands 16, 24 may be of any suitable material, such as silk. Silk is less likely to slide during use. Thus, strand 24 extends through hole ~~27~~ 19 in upper support base 32, down through aligned hole 39 in support plate 33, about the underside of spring beam 35 (which thus provides tension when strand 24 is tied), up through hole 40 in support plate 33, and through aligned hole ~~29~~ 21 in support base 32 and upwardly as shown. Alternatively, all strands could extend up and be knotted at the respective holes 19, ~~20~~ 21 or glued to the underside of the support plate ~~35~~ 33.

[0031] As discussed, any suitable materials may be used, such as a fabric material for pad 25 with a base 14 of polycarbonate or similar material glued to pad 25. The radiused edges 38 of the holes eliminate sharp cutting edges. Strands or sutures 16, 24 may be No. 1 braided silk sutures. Support base 32 ~~Pad 34~~ may be of any suitable polymeric material, such as a material of about 35A Durometer.

[0032] As seen in Figure 4, upper support base 32 is slightly concave at its middle 100.

[0033] Looking at Figure 2, the connector 12 has a main hub portion 101 having an inlet port 102 at one end for insertion of a catheter (not shown) therein and an elongated tubular portion 103 extending therefrom for fluid instillation. Hub portion 101 also has an apertured ear

104 on one side of the hub portion 101 ~~tubular portion 103~~ and a flexible inlet tube 105 fluidly coupled to hub portion 101 for introducing fluids and directing an inserted catheter or wire therein, as is well known in the art. Of course, any suitable connector or catheter configuration may be used.

[0034] As seen in Figure 2, connector 12 rests in the middle or concave portion 100 of upper support base 32. The protrusions 34 assist in holding the connector 12 in position. The strands 16, 24 extend through the aligned holes in upper support base ~~34~~ 32 and lower support plate 33 and under beams 35.

[0035] Connector 12 may have one or more spaced annular grooves, such as grooves 106, 107 (Figure 2). Strands 16, 24 may be tied to connector 12 in any suitable manner. For example, strand 16 may first be extended through the hole in apertured ear 104, then wrapped around groove 106 and the free ends tied. Strand 24 may be wrapped around groove 107 and the free ends tied. The overall length of one side of each strand may be easily adjusted to accommodate tying.

[0036] Although a particular type of connector is disclosed, having annular grooves, obviously any suitable type of connector may be used as long as strands 16, 24 can be wrapped around or through the holes and tied. The hardened ends 22 allow easy insertion through the aligned holes and the apertured ear.

[0037] The concave center 100 of upper support base 32 acts as an anti-roll channel for connector 12. This also prevents folding of the base 32 in the center.

[0038] Although 2 strands 16, 24 may be used to tie connector 12 to base 32, obviously one may be used. Thus, at least one strand is sufficient utilizing the teachings of the invention.

[0039] In a further embodiment of the invention, wherein like numerals refer to like parts of Figures 1 to 4, as seen in Figure 5, base 110 otherwise identical to base ~~32~~ 14, may have the upper surface 111 of upper support base 112 slightly raised, at its center 113, so that when connector 12 is secured in position, the inlet port 102 is in a slightly elevated position for easy insertion of a catheter into a connector mounted thereon (not shown).

[0040] Circular holes with radiused sides have been disclosed, as seen in Figure 6, wherein like numerals refer to like parts of Figures 1 to 4, the holes for passage of the strands therethrough may include hole portions 200 extending through tabs or ears 201 which may be cut

out of the support base and support plate or a single structure comprising both support base and support plate as disclosed below. The hole portions 200 communicate with aligned holes through the remaining portions of the base 14. The tabs 201 will thus flex slightly when the strands are pulled through the hole portions 200 and thereby exert a downward force through the strand on the connector once the strands are tightened around and/or over the connector. An upward force on the tabs forces the support base and plate to contour around the connector and thus prevents rolling of the device on the base.

[0041] In still another embodiment of the invention, as seen in Figure 7 wherein like numerals refer to the embodiment of Figure 1, base 14 may have hemispherically shaped protrusions, such as protrusions 300, extending upwardly therefrom instead of conically shaped protrusions. Also, as seen in Figure 8, wherein like numerals refer to like parts of Figure 1, tabs 400, ~~401~~ 400' with holes 401, 401', respectively, therethrough, similar to tabs 201 and holes 200 in Figure 6, may be provided on the upper surface of base 402. The area 403 is concave but raised slightly at the midpoint 404 thereof to provide a ramp for a connector or the like. That is, the area 403 may slope upwardly from one side ~~403~~ 403' to midpoint 404, then slope downwardly from midpoint 404 to the other side 405'. In this embodiment, a single strand 405, otherwise identical to strands 16, 24, Figure 9, may extend up through one hole 401, knotted on the underside of the lower support plate ~~25~~ 33, as at knot 406, extend through hole 401 in the tab 400 as shown, then extends through hole 401' in post 400' and tied back upon itself, thus retaining a connector or the like (not shown).

[0042] The strands may be of silk or any flexible material that is substantially non-extendible about its long axis. The flexible beam 35 conforms to the shape of a connector mounted on the base and creates and maintains tension in the strands so as to keep any knots tight and pulls or presses the connector into the conforming surface preventing rolling. Also, beam 35 may be integral with plate ~~25~~ 33 and base 32 with the hardness of the securement base 14 varying from the top to bottom thereof or of uniform hardness to allow both the cushioning/conforming effect of said base and the springlike character of said plate.

[0043] Although a particular embodiment of the invention is disclosed, variations thereof may occur to an artisan and the scope of the invention should only be limited by the scope of the appended claims.